IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

BEST MEDICAL INTERNATIONAL, INC. Plaintiff, vs. ACCURAY, INC., a corporation; Defendant.	Case No. 2:10-CV-1043 (TFM)

ACCURAY'S SUR-REPLY CLAIM CONSTRUCTION BRIEF

Kirsten R. Rydstrom
PA ID No. 76549
REED SMITH LLP
225 Fifth Avenue
Suite 1200
Pittsburgh, PA 15222
(412) 288-7284
(412) 288-3063 (fax)
krydstrom@reedsmith.com

Madison C. Jellins
HelixIP LLP
400 Seaport Court
Suite 105
Redwood City, CA 94063
650-474-0240
mcjellins@helixip.com

Janice A. Christensen
HelixIP LLP
New York
Counsel for Defendant,
Accuray Incorporated
650-474-0240
jchristensen@helixip.com

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I. INTRODUCTION

After dragging Accuray through this litigation for almost two years, and changing counsel multiple times, BMI confirms what Accuray has said all along. BMI has no case. BMI demonstrates through its briefs that it does not understand its own patent, does not understand the underlying technology, and does not even attempt to try.[1] BMI's version of claim construction is a mechanistic, barely linguistic exercise of defining isolated claim terms by using Webster's dictionary. But Merriam Webster is not an authority on the complex field of radiation therapy treatment planning, and it is inconceivable that such complex technology could be understood based on dictionary definitions alone. Moreover, BMI's isolated constructions do not explain what the inventor invented. BMI apparently does not know because it provides no explanation that would help the court understand the claims. BMI does not even address the background of the technology. To explain a complex, cutting edge field that saves lives, BMI relies only on dictionaries.[2]

BMI heavily criticizes Accuray for using extrinsic evidence to help the Court understand the technology. In response to Accuray's expert declaration and citation to multiple technical articles to explain the background of the technology, BMI spends nine pages of its brief arguing that such extrinsic evidence is improper and irrelevant. But how can the court educate itself to the level of one of skill in the art without the help of relevant technical articles and an expert who was working in the field at the time the patent application was filed? The '283 patent cannot be interpreted from the layperson's perspective – it involves a specialized technology that requires

[1] A perfect example is BMI's repudiation of the Corvus/Peacock as exemplary of the invention. Nine months ago, BMI's position was the polar opposite: then, BMI stated that Corvus/Peacock was the conception of the invention.

[2] It is too late for BMI to remedy its omission in the *Markman* hearing. BMI is limited to the extrinsic evidence cited in its briefs and listed in its extrinsic evidence list per LPR 4.3. Accuray will move to strike any additional extrinsic evidence submitted by BMI in the form of a tutorial or expert.

at a minimum, an understanding of complex optimization algorithms, radiation physics, and treatment delivery. BMI, the patent owner, has provided absolutely no explanation to help the Court understand its purported invention. In fact, BMI does not engage on the technology at all. With the absence of any discussion of the technology in BMI's opening or reply claim construction briefs, Accuray's explanation of the background of the technology and the state of the art is undisputed.

BMI must recognize that if Dr. Rosen is not a proper expert, no one is. Dr. Rosen has the requisite credentials; was working in the field from 1975 to the present; knew the principal inventor, Mark Carol, and Dr. Webb; and participated in the Durango NOMOS workshop in 1996, at which Dr. Carol disclosed his work. Nor does BMI disagree with any particular point of Dr. Rosen's substantive discussion of the technical field of radiation therapy planning. BMI admits that "a full 22 pages of the Rosen Declaration represents a tutorial on the area of radiation therapy," which is precisely the intended purpose of his declaration and for such expert testimony. Although BMI views the tutorial with suspicion, it has countered with no expert of its own, nor has it made substantive objections with regard to Dr. Rosen's explanation of the background of the technology.

BMI also argues that the technical articles cited by Accuray and by its expert, Dr. Rosen, are "irrelevant." These technical articles, including articles by Dr. Webb, Dr. Carol, and other experts in the field, were published contemporaneous with or earlier than the filing date of the patent, and are evidence of the state of the art. Significantly, BMI ignores the Webb articles incorporated by reference in the '283 patent. The Court should ask BMI why it ignores Webb. The Webb articles are the sole disclosure of how the only optimization algorithm disclosed in the patent (SARP) generates and changes "proposed radiation beam arrangements." Moreover,

Webb's work, which was never patented and was publicly available, was the foundation on which the principal inventor, Dr. Mark Carol, built the NOMOS radiation therapy planning technology – as both Dr. Carol and Dr. Webb agree. It is disingenuous for BMI to pretend now that Webb's work either does not exist or that it is "irrelevant" to the '283 patent. Without the Webb articles, the patent has no disclosure of an optimization algorithm sufficient to support the claims.

BMI argues that Accuray's proposed claim constructions are based only on extrinsic evidence, but nothing could be further from the truth. Accuray has used the methodology set forth in *Phillips*, focusing on the claims and the written description, as the primary source of claim meaning. Accuray started with the language of the claims, and provided numerous citations to the specification to explain what the claims mean. Instead of using Webster's, Accuray used the specification as the dictionary, as required under *Phillips*. Accuray uses extrinsic evidence only to complement the intrinsic evidence: to explain the background of this complex technology, the state of the art, and how one of skill in the art would have understood the patent at the time the '283 application was filed.

Faced with a comprehensive analysis of the claims in the context of the most relevant intrinsic and extrinsic evidence, it is BMI who is flailing. Having relied only on dictionary definitions, it now is belatedly trying to find some support for its constructions in the specification. BMI never engages in substantive arguments about why Accuray's proposed constructions are wrong. It does not use the specification to show that the technology is other than Accuray says it is. BMI provides no logical technical basis for the Court to conclude that its proposed constructions are correct.

Finally, BMI apparently has given no thought to what happens if it is successful in obtaining its "plain meaning" claim construction. Its construction is so broad that its claims will be rendered invalid in view of virtually every prior art reference that addresses radiation treatment planning. Clearly, the Patent Office would never have allowed such a patent to issue with the construction proposed by BMI. Given the choice between two constructions – a construction so broad it renders the claim invalid and a narrower construction fully supported by the specification, the technical articles incorporated by reference, and the inventor's contemporaneous disclosure of the invention – the Court must choose the second construction. Only Accuray's construction is consonant with "what the inventor actually invented."

II. BMI's Attempt to Counter the Rosen Declaration with A Posting on A Message Board Should Be Stricken

BMI's only attempt to rebut the Rosen Declaration is based on a random posting on a message board, purportedly from a doctor, stating that, because all CK planning is inverse planning … "the exact algorithm used is probably not particularly important." (Doc. No. 142 at p. 6, footnote 5) BMI is apparently arguing that Accuray's proposed construction limiting the claims to SARP would not preclude infringement by the CyberKnife because the CyberKnife could conceivably use SARP rather than the algorithms it actually does use. BMI infers from this comment that "presumably, that would include the SARP algorithm."

BMI wields the random musings of someone on a message board as if it were the statement of a pseudo-expert. The comment, however, is an out-of-court statement offered for its truth by someone who is not subject to cross-examination. The message board has not been established to be a reliable source, and there is no way to test the reliability of the statement, or whether the author has the experience to understand the algorithms Accuray uses. Infringement cannot be based on such random musings. Moreover, all of the research for the last twenty years or more

on radiation treatment planning using different combinations of cost functions and mathematical algorithms would suggest the opposite conclusion. Accordingly the comment cannot rebut Accuray's position or counter the declaration of an esteemed expert like Dr. Rosen, and should be stricken. After almost two years, the sum total of BMI's support for its infringement case against Accuray amounts to the Kilby article, some dictionary definitions, and a message board posting. BMI's case is so flimsy it collapses like a house of cards.

III. Dr. Rosen's Declaration is Consistent with and Supported by the Intrinsic Evidence

A. BMI's Insinuations that Dr. Rosen Is Not a Proper Expert Should be Rejected

BMI does not even attempt to defend its defective claim constructions or its inability to describe what the inventors actually invented. Instead, BMI expends much ink trying to challenge the propriety of Dr. Rosen's declaration, seeking to strike it "in its entirety," without commenting on the substance of Dr. Rosen's testimony, submitting a competing expert declaration, or offering its own explanation of the technology. (Doc. No. 142 at pp. 4-9).

BMI does not – and cannot – attempt to disqualify Dr. Rosen as an expert based upon his credentials.[3] Dr. Rosen has worked in the field of the claimed invention as a Radiation Physicist for over 35 years. (Rosen Decl. ¶¶ 1-7)[4] Dr. Rosen spent about 14 years of his career researching the mathematical optimization of radiation therapy treatment plans. (Rosen Decl. ¶ 9) Based upon his work in this area, he authored 17 peer-reviewed publications and 5 book chapters on mathematical optimization of radiation treatment plans. (Rosen Decl. ¶ 9) He also gave over 20 presentations on this topic at national and international conferences, including at

[3] BMI generally cites *Daubert v. Merrill Dow Pharms, Inc.,* 509 U.S. 579, 595 (1993), but BMI does not purport to ask the Court to disqualify Dr. Rosen based upon his credentials or any scientific methodology.

[4] All references herein to "Rosen Decl." refer to the Declaration of Dr. Isaac I. Rosen, at Doc. No. 138, Ex. 24.

the 1st NOMOS IMRT Workshop ("Durango Conference"). (Rosen Decl. ¶¶ 108-109) The Durango Conference was hosted by named inventor Mark Carol and his company, NOMOS, on May 17-18, 1996 in Durango, Colorado. Dr. Carol and NOMOS invited the world's leading physicists and physicians in the field of radiotherapy to speak at this conference, which showcased the state of the art at the time and the latest advancements in the field. (Rosen Decl. ¶109) At the Durango Conference, Dr. Rosen presented a paper on treatment planning for intensity modulated radiation therapy. (Rosen Decl. ¶ 109)

Dr. Rosen has also researched other aspects of radiation therapy treatment planning, software development, radiation dosimetry, intensity-modulated radiation therapy (IMRT), and quality assurance in radiation therapy. These research projects resulted in an additional 72 peer-reviewed publications, 7 book chapters, and numerous presentations at national and international meetings. (Rosen Decl. ¶ 10) He has also chaired scientific sessions at national and international conferences. (Rosen Decl. ¶ 10) Dr. Rosen has B.S., M.S. and Ph.D. degrees in Physics, and has been a Professor of Radiation Physics for nearly 30 years. (Rosen Decl. ¶¶ 1-8) He is also a Fellow of the American Association of Physicists in Medicine, Board Certified in Therapeutic Radiological Physics by the American Board of Radiology, Board Certified in Radiation Oncology Physics by the American Board of Medical Physics, and licensed by the Texas Board of Licensure for Professional Medical Physics."). (Rosen Decl. ¶ 8)

Dr. Rosen is clearly qualified to serve as an expert on the technology at issue in this case. Indeed, he lived through much of the history of this technology and his work helped to shape it into what it is today. If Dr. Rosen were deemed to be unqualified to serve as an expert in this case, no one would qualify.

B. In A Complex Field of Technology, Expert Testimony Concerning the Background of the Technology and State of the Art May Be Helpful

Dr. Rosen's testimony provides background and context for Accuray's constructions. Notwithstanding BMI's efforts to trivialize the field of the invention, radiation physics is a highly specialized area requiring an advanced degree in physics or the equivalent and many years of advanced training. The technology is not intuitive, nor can it be understood in any meaningful way by resort to English language dictionaries. BMI concedes that the majority of the Rosen Declaration "represents a tutorial on the area of radiation therapy." (Doc. No. 142 at p. 6) Presenting a technical tutorial to educate the Court is appropriate given the complexity of the technology at issue, and is permissible under this Court's Local Rules. *See* LPR 4.3 (permitting parties to present expert testimony in support of proposed claim constructions). The Special Master's Claim Construction Hearing Order also provides for expert testimony on claim construction in this case. (Doc. No. 62) Federal Circuit precedent gives this Court discretion to consider expert testimony if it would be helpful. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*); *Markman v. Westview Instr., Inc*., 52 F.3d 967 (Fed. Cir. 1995) (en banc). Accuray submitted Dr. Rosen's declaration in an effort to provide some background and explanation of the complex technology at issue in this case. Even in the absence of Dr. Rosen's testimony, Accuray's proposed claim constructions have full intrinsic evidentiary support and stand on their own.

BMI complains that Dr. Rosen's testimony is somehow at odds with the purported "plain and ordinary meaning" of the claim terms at issue – a "meaning" that BMI has pulled from the pages of Merriam Webster's English language dictionary. (Doc. No. 142 at pp. 3, 7) While Dr. Rosen's testimony may not support the English language dictionary definitions advanced by BMI, it is entirely consistent with the '283 patent specification, the Webb articles (incorporated

by reference into the specification at Col. 12:34-45),[5] the file history, and the general knowledge and state of the art at the time the '283 patent was filed, as reflected in the contemporaneous writings of named inventor Mark Carol and the written proceedings of the patentees' "Durango Conference" held prior to the filing of the '283 patent.

The Federal Circuit has explained that "extrinsic evidence in the form of expert testimony can be useful for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, [or] to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art." *AIA Eng'g Ltd. v. Magotteaux Int'l S/*A, 657 F.3d 1264, 1273 (Fed. Cir. 2011); *see also Phillips,* 315 F.3d at 1319 (extrinsic evidence such as expert testimony "can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean.").

This is the purpose of Dr. Rosen's declaration – to provide background on the complex technology at issue in this case and to assist the Court in understanding the technical aspects of the patent as the skilled artisan would understand them. Dr. Rosen's declaration explains, for example, what radiation therapy is and how it works (Rosen Decl. ¶¶ 30-41); the background of intensity modulated radiation therapy and multileaf collimators (Rosen Decl. ¶¶ 42-52); the background of treatment planning (Rosen Decl. ¶¶ 53-64); the background of optimization algorithms and cost functions and how they work (Rosen Decl. ¶¶ 65-93); the background of beam weight optimization in radiation therapy (Rosen Decl. ¶¶ 94-102); the events and history leading up to the filing of the '283 patent, including the named inventor's work leading up to the filing of the patent, Dr. Webb's work in simulated annealing, and the "Durango Conference"

[5] All references herein to the '283 patent-in-suit refer to Doc. No. 131, Ex. 1.

hosted by NOMOS (Rosen Decl. ¶¶ 103-114); and his understanding of certain terms and phrases in the patent as one who practiced in the field at the time of the invention (Rosen Decl. ¶¶ 115-134). This information is highly relevant to the invention story, *i.e.,* what was already known in the art at the time of the invention, the evolution of the technology and what it is that Dr. Carol actually invented. *Phillips*, 415 F.3d at 1312-13; *Retractable Techs., Inc. v. Becton Dickinson and Co*., 653 F.3d 1296 (Fed. Cir. 2011).

C. Dr. Rosen's Declaration is Tied to the Intrinsic Record

BMI cites generally to *Biagro* and *Network Commerce* for the proposition that Accuray is attempting to "reconceptualize the claims," but neither of these cases supports BMI's argument. A closer reading of the facts of these cases supports Accuray's view that the Court can look to expert testimony in claim construction if it is considered in the context of the intrinsic record, as it is here. *Biagro Western Sales, Inc. v. Grow More, Inc*., 423 F.3d 1296, 1302 (Fed. Cir. 2005); *Network Commerce, Inc. v. Microsoft Corp.,* 422 F.3d 1353, 1361 (Fed. Cir. 2005).

In *Biagro*, the expert's testimony was completely unsupported by the intrinsic record. Biagro relied on its expert to show that that those skilled in the art would understand that the amounts of plant nutrients in fertilizer products are frequently expressed as "chemical equivalents." *Biagro,* 423 F.3d at 1302-04. However, "nothing in the patent or prosecution history indicate[d] that labeling standards are relevant to the claimed fertilizer, and nothing in Biagro's extrinsic evidence suggest[ed] that a person skilled in the art of fertilizer formulation would necessarily use a chemical equivalent to express the amount of phosphorous acid in a fertilizer that does not actually contain phosphorous." *Id.*

In *Network Commerce*, the expert's testimony was also "at odds with the intrinsic record." 422 F.3d at 1361. Specifically, the expert in *Network Commerce* testified that the claimed "download component" need not contain a boot program. However, the specification

made clear that the download component must include a boot program, and that the boot program interacts directly with the operating system of the computer without the assistance of any other program. The expert's testimony was rejected because it was clearly contradicted by the express teachings of the specification. *Id.* at 1360-62.

Unlike the facts in *Biagro* and *Network Commerce*, Dr. Rosen's testimony is fully consistent with and supported by the specification. Dr. Rosen's explanation of the background of the technology is supported by Dr. Webb's articles (which are incorporated by reference into the specification of the '283 patent at Col. 12:34-45) and contemporaneous publications by named inventor Mark Carol relating to his claimed invention. *See, e.g.,* Rosen Decl. at ¶¶ 75, 86, 88, 91, 92, 105, 106, 109, 110, 121, 122, 123, 124, 128 (citing Dr. Webb's articles) and ¶¶ 64, 101, 103, 105, 106, 107, 109, 111, 112, 113, 114, 129 (citing Dr. Carol's articles).

Dr. Rosen's discussion of the patent claims is likewise supported by the specification, Dr. Webb's articles, and Dr. Carol's contemporaneous publications. For example, Dr. Rosen explains in ¶ 120 of his declaration, by reference to the specification, that "there are essentially three components to the inverse planning method presented in the patent: the computer configured to run an optimization algorithm for finding the optimum beam weights [e.g., C7, L11-L25], the method of user definition of the treatment planning goals [e.g., Figure 5, C10, L53 - C11, L8], and the cost function that mathematically describes the goal of optimization [e.g., C13, L10-39, Figure 3 and 4]."

As another example, in ¶¶ 121-123 of his declaration, Dr. Rosen explains that "Dr. Webb's 1989 article, incorporated by reference in the specification of the '283 patent, explains that the simulated annealing algorithm is used to obtain a proposed set of beam weights." *See* Col. 12:34-45. Citing to Column 13 of the specification, Dr. Rosen further explains that "[o]ne

skilled in the art would have understood that the cost function claimed in the '283 patent is the specific cost function described in Column 13, in light of the specification, the Webb articles, and knowledge and experience in the field." (Rosen Decl. ¶ 124) In ¶ 125, Dr. Rosen discusses the specific cost function described in Column 13 of the '283 patent. (Rosen Decl. ¶ 125) In ¶ 126, he explains that the specification teaches that the cost function described in Column 13 is incorporated into the simulated annealing algorithm and that the specification does not teach how to use this cost function with any other optimization algorithm. (Rosen Decl. ¶ 126) Thus, ***based upon his review of the '283 patent specification and the Webb articles (incorporated by reference)***, Dr. Rosen concludes in ¶ 128 that "[g]iven that there is no disclosure of any optimization algorithm other than simulated annealing (and its variants, such as fast simulated annealing) in the '283 patent or the Webb articles, and that it would have been difficult to figure out a way to use the cost function of the '283 patent with any algorithm other than simulated annealing, one skilled in the art would understand that claims 25 and 29 are limited to a computer that runs a simulated annealing algorithm." (Rosen Decl. ¶ 128) Each of Dr. Rosen's opinions on the '283 patent claims are similarly tied to the intrinsic record.

D. BMI's Objections to the References to Corvus and Peacock are Belied by its Earlier Admissions that Corvus and Peacock Exemplify the Claimed Invention

Curiously, BMI objects to Dr. Rosen's reference to NOMOS's "Corvus" treatment planning system and its predecessor, the "Peacock" system. BMI argues that the Corvus and Peacock systems are irrelevant to the patent-in-suit, and characterizes them as "other inventions by the inventor, Dr. Carol." (Doc. No. 142 at p. 7) Earlier in this case, however, BMI took a very different position, and represented that the Corvus system embodies the claimed invention of the '283 patent. In fact, when pressed to produce "***all documents evidencing the conception and reduction to practice, design and development of each claimed invention,***" pursuant to

LPR 3.1, BMI produced manuals for the ***Corvus*** system. *See* Doc. No. 71 at pp. 1-2, 5-6. When Accuray requested the production of conception and reduction documents from the proper time frame (*i.e.* prior to the filing date of the patent), BMI agreed that "as the precursor to the Corvus Treatment System, there should be earlier Peacock research and development documents existing. Just as there should be documents evidencing sale or offer to sell the claimed invention prior to the date of application for the patent in suit." (Doc. No. 71 at p. 2 and Exhibit 4 thereto). BMI represented that it had produced documents evidencing the conception, reduction to practice, design and development of the claimed invention" which "include references and support for the Corvus System predecessor, Peacock system." (Doc. No. 74 at pp. 2-3). In view of BMI's earlier admissions that the Peacock and Corvus systems evidence the conception, reduction to practice, design and development of the claimed invention of the '283 patent, its current argument that "these inventions can shed no light on what was intended by the patent at issue and its particular claims" (Doc. No. 142 at p. 7) must be soundly rejected.

BMI argues that the Peacock and Corvus are not mentioned in the patent specification or claims, and "the absence of such references supports Best Medical's interpretation that the claims are not so limited." (Doc. No 142 at p. 7) BMI is mistaken. The Figures in the '283 patent refer to NOMOS' Peacock and Corvus technology. For example, Figure 2 states: "Strength of Arcs Normalized for Consistent Dose." *See* Ex. 2 at pp. 56-57.[6] Figure 5A at the top states, "Treatment Machine, Nomos Library 6MV."[7] As BMI must know, the NOMOS Library 6MV is a library of beams used with the NOMOs Corvus planning system. It contains parameters that describe the treatment machine, including a description of the fixed gantry

[6] All references to Exhibits 1 through 24 herein refer to Exhibits 1 through 24 of Accuray's Responsive Claim Construction Brief (Doc. No. 138, Ex. 1-24).
[7] Note that Treatment Machine and Immobilization are separate from the Planning Goals.

positions. The arc is typically 270 degrees, with beam positions at every 5 degrees.[8] *See* Figure 5A, which states "Immobilization: Talon on NomoGrip." The Talon NomoGrip system is an immobilization and localization device used in the Nomos-Peacock IMRT system with the Corvus Treatment Planning software.[9] *See* Figure 5B, which states at the top, "Treatment Complexity, 1 cm Slices," and at the bottom, "Simulated Annealing Parameters, Iterations, Start grain, End grain." Both Peacock and Corvus use simulated annealing, and treatment is done in 1- 2 cm slices.[10]

E. BMI's Objections to Dr. Rosen's Declaration as Litigation Generated and Biased Are Not Well Founded

BMI's objections to Dr. Rosen's declaration as "litigation generated" and "biased" are also unfounded. (Doc. No. 142 at pp. 3, 5). By their nature, expert testimony is "litigation generated." The fact that testimony is provided during the course of litigation is not a basis for excluding it. Further, the Federal Circuit has expressly held that expert testimony may be submitted to assist the Court in claim construction. *Phillips*, 415 F.3d at 1318-19 (because expert testimony can help educate the court regarding the field of the invention and help the court determine what a person of ordinary skill in the art would understand the claim terms to mean, the district court in its sound discretion may admit and use such evidence).

The only "evidence" that BMI relies on in making its bias accusations is that Dr. Rosen is being compensated for his work on this litigation at a rate of $350 per hour and that Dr. Rosen works for the Methodist Hospital in Houston, which owns a "TomoTherapy" system. (Doc. No. 142 at p. 5) Expert witnesses are routinely compensated for their work in litigation. *See* Fed. R. Civ. P. 26(a)(2)(B)(vi) (requiring expert report to disclose "the compensation to be paid for the

[8] *See* Ex. 2 at pp. 56-57.
[9] *See* Best Medical website, at www.teambest.com/news/NOMOS_multipanel_brochure.pdf.
[10] *See* Ex. 2, at 56-57; Ex.5.

study and testimony in the case."). The fact that an expert is compensated for his time is not a basis for striking his testimony.

BMI also makes much of the fact that Dr. Rosen's employer, the Methodist Hospital, owns a TomoTherapy device. Accuray recently acquired TomoTherapy, Inc. and its product line in June, 2011, well after this suit was filed. BMI has not alleged that Dr. Rosen is even aware that the Tomo product line is now owned by Accuray or such information would impact any of his opinions. BMI neglects to mention that the Methodist Hospital also owns equipment sold by a number of Accuray's competitors. BMI has not set forth any plausible basis to conclude that the hospital would prefer one vendor over another, much less to show that Dr. Rosen would have a connection to any of the hospital's vendors. BMI's vague innuendos do not provide any basis to exclude his testimony.

IV. The Technical Publications Cited by Accuray and Dr. Rosen Are "Tied to the Specification"

A. Dr. Webb's Articles Are Incorporated by Reference in the Specification and Cited in the File History

BMI tries to distance itself from Dr. Webb's articles and, to that end, attempts to characterize them as "irrelevant extrinsic evidence." But Dr. Webb's articles are not at all "irrelevant," nor are they "extrinsic publications" as BMI alleges. Dr. Webb's articles are incorporated by reference into the '283 patent specification and listed on the face of the patent. As such, they are part of the ***intrinsic*** record. Further, Dr. Webb's articles provide the ***only*** description of an optimization algorithm in the '283 patent. Other than the description of simulated annealing in Dr. Webb's articles, the '283 patent does not describe, for example, how to "computationally obtain a proposed radiation beam arrangement," "computationally change the proposed radiation beam arrangement iteratively," or "change the beam weights" as recited in Claims 25 and 29. The specification explicitly directs the public to the Webb articles to

understand these aspects of the claims. *See* '283 patent, Col. 12:34-45.[11] BMI's suggestion that Accuray "cannot tie [Dr. Webb's articles] to the patent or the claim language" – when these articles are cited in the file history of the patent and incorporated by reference in the specification itself – is completely disingenuous and must be rejected. (*See* Doc. No. 142 at p. 9)

B. Dr. Carol's Contemporaneous Publications Mimic the Specification

BMI's objection to Dr. Carol's articles is also without merit. As mentioned above, Dr. Carol is a named inventor on the patent-in-suit. Contemporaneous with the filing of the '283 patent, Dr. Carol published several articles describing radiation treatment planning optimization. Accuray and Dr. Rosen cite two of Dr. Carol's articles that were published in a book describing the proceedings of Nomos' "1st IMRT Workshop" hosted by Dr. Carol in May, 1996 in Durango, Colorado.[12] Accuray and Dr. Rosen cite two additional articles by Dr. Carol published around the filing date of the time the '283 patent.

Far from "irrelevant," Dr. Carol's publications explain the background of IMRT and state of the art at the time. Dr. Carol's publications also explain treatment planning optimization and in the Peacock system (which BMI has identified in this case as evidence of the "conception and reduction to practice" of the claimed invention of the '283 patent). In fact, Dr. Carol's May, 1995 article describes a treatment planning system that is virtually identical to the subject matter of the '283 patent, and includes nearly every element of claims 25 and 29. (Ex. 2 at pp. 57-58)

Further, portions of Dr. Carol's 1997 article (Ex. 3) track the "Detailed Description of the Invention" set forth in the '283 patent specification almost verbatim, as shown in the illustrative

[11] The patentees submitted a third Webb article to the Patent Office during the prosecution of the '283 patent, entitled "Optimization of Simulated Annealing of Three-Dimensional Conformal Treatment Planning for Radiation Fields Defined by a Multileaf Collimator," S. Webb; Phys. Med. Biol. 1991, vol. 36, no. 9, pp. 1201-1226. This article is cited on the face of the '283 patent and is part of the intrinsic record. (Ex. 20)

[12] *See* Doc. No. 138, Exs. 2-5.

example below:

Excerpts from Dr. Carol's 1997 Article	Corresponding Excerpts from '283 Patent Specification
"By assigning different weights to different zones under the CDVH curve, different results can be obtained. Therefore, it is crucial that the weights are picked with an outcome in mind, and that the user understands what kind of results the assigned weights will produce." (p. 318)	"By assigning different weights to different zones of the CDVH curves, different results can be obtained. Therefore, the weights are incorporated into the software with an outcome in mind, and the user must understand what kind of results the assigned weights will produce." (Col. 13:53-57)
"For BP structures, zones 4, 5 and 8 are important, with zone 8 (maximum dose received by any portion of the structure) being the most important. For BU structures, where maximum dose is not important as long as the desired volume of structure falls under the entered limit, only zone 4 is important. Thus BP structures are assigned high weights to zone 4, 5 and 8 while BU structures receive high weights only in zone 4." (p. 318)	"For a BP structure, zones S4, S5, and S8 may be chosen as important, with zone S8 representing the maximum dose received by any portion of the structure being chosen as the most important zone for that type of structure. For a BU structure, where maximum dose is not important as long as the desired volume of structure falls under the chosen limit, only zone S4 may be important. Thus, high weights are chosen for zones S4, S5, and S8 in BP structures. Similarly, high weights may be chosen for BU structures only in zone S4." (Col. 14:32-41)

For additional examples, *see* Ex. 25. As Dr. Carol's 1997 article largely mimics the "Detailed Description of the Invention" in the '283 patent, it is undoubtedly tied to the specification and certainly should be considered relevant.

C. Additional Publications Are Useful to Explain the Background and State of the Art

BMI's objection to the remaining articles cited by Accuray and Dr. Rosen is equally without merit. *See* Doc. No. 142 at pp. 34-36 (listing articles to which BMI objects). Each of these articles are relevant to show, at a minimum, the background and state of the art of the time the '283 patent was filed. The Court is permitted to consider these references in its claim construction analysis under *Markman*, *Phillips* and their progeny. *Markman*, 52 F.3d at 980; *Phillips*, 415 F.3d at 1317-18. Particularly in a complex field such as radiation physics, this type

of evidence showing the background and state of the art can be helpful to the Court. The Court has leeway to weigh this evidence as it deems appropriate. *Emcore Corp. v. Optium Corp.,* No. 6-1202, 2008 U.S. Dist. LEXIS 59794, at *18 (W.D. PA. 2008) (holding that district courts are authorized to rely on extrinsic evidence in construing claims and "what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law."). Dr. Rosen properly relied on these references, as well as the Webb articles and the Carol articles, in forming his conclusions.

V. BMI Cannot Use the Doctrine of Claim Differentiation to Broaden the Claims Beyond What the Inventors Actually Invented

BMI resorts to the doctrine of claim differentiation to argue that (1) that an "optimized radiation beam arrangement is not limited to the SARP algorithm" and (2) that "partial volume data and CDVH curves are not interchangeable." (Doc. No. 142 at pp. 14, 27-28) However, the clear teachings of the specification contradict BMI's argument and cannot be overridden by the limited doctrine of claim differentiation. *Marine Polymer*, 2012 U.S. App. LEXIS 5567, at * 1 (where there is a conflict between the teachings in the specification and the doctrine of claim differentiation, such conflict is resolved in favor of the specification) ; *Curtiss-Wright Flow Control Corp., v. Velan, Inc*., 438 F.3d 1374; 1380-81 (Fed. Cir. 2006) (holding that claim differentiation is a "limited tool of claim construction.").

The doctrine of claim differentiation is based on the premise that dependent claims are presumed to be narrower in scope than the independent claim from which they depend. *Id*. BMI argues that the term "optimized radiation beam arrangement" in claims 25 and 29 should not be limited to the SARP algorithm because claims 3, 5, 15, 19, 43 and 45 recite that "the optimized radiation beam arrangement is calculated using simulated annealing radiation therapy planning methods." (Doc. No. 142 at p. 14) BMI fails to appreciate, however, that none of these claims

depend from claims 25 or 29, nor are they even related to claims 25 and 29 through any chain of dependency. These claims are already different in scope, because claims 25 and 29 are ***apparatus*** claims, whereas claims 3, 5, 15, 19, 43 and 45 are ***method*** claims. No claims depending from apparatus claims 25 and 29 include SARP as an additional limitation. BMI's argument that construing "optimized radiation beam arrangement" as limited to the SARP algorithm would somehow render claims 25 and 29 identical in scope to other claims in the '283 patent must be rejected.

Further, even if limiting the "optimized radiation beam arrangement" to the SARP algorithm rendered claims 3, 5, 15, 19, 43 and 45 redundant (which it does not), the doctrine of claim differentiation does not require a different construction, because the specification does not describe or enable any optimization algorithm other than SARP. *See, e.g.,* Doc. No. 138 at pp. 19-21, 24. *Edwards Lifesciences LLC v. Cook Inc.,* 582 F.3d 1322, 1330 (Fed. Cir. 2009) ("Even if the claim construction had rendered the dependent claim redundant, the doctrine of claim differentiation does not require us to give the "graft" devices their broadest possible meaning."); *Nystrom v. Trex Co., Inc.,* 424 F.3d 1136, 1143-45 (Fed. Cir. 2005); *Marine Polymer,* 2012 U.S. App. LEXIS 5567, at *18 ("[C]laim differentiation is "not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history.").

BMI similarly argues that the construction of the term "partial volume data" in claims 25 and 29 should not incorporate "CDVH curves" because dependent claim 26 includes a limitation requiring CDVH curves. (Doc. No. 142 at pp. 27-28) Again, BMI's claim differentiation argument fails because it is contrary to the teachings of the specification. The specification consistently refers to partial volume data and CDVH curves interchangeably. *See* Doc. No. 138, at 42-44. In other words, the partial volume data can be used to construct a CDVH or the CDVH

can be used to generate partial volume data. *See, e.g.,* Col. 5:3-8; Col. 6:43-46; Col. 7:4-5; 7:29-30; Col. 7:66-8:14.

Where, as here, the specification dictates a particular construction, the doctrine of claim differentiation does not trump the clear import of the specification. *Eon-Net LP v. Flagstar Bancorp.,* 653 F.3d 1314, 1323 (Fed. Cir. 2011). ("Claim differentiation, however, is simply 'a rule of thumb that does not trump the clear import of the specification.'"); *Curtiss-Wright,* 438 F.3d at 1381 ("Second, relying on the claim differentiation presumption in this case contradicts the correct meaning of claim 14…. Any construction to the contrary is not consistent with the overall context of this invention and this field of art as described in the specification."); *Lydall Thermal/Accoustical, Inc. v. Federal-Mogul Corp.*, No. 2009-1135, 2009 U.S. App. LEXIS 20077, at *16-17 (Fed. Cir. 2009); *Nystrom*, 424 F.3d at 1143-44 (holding that "[a]n examination of the term "board" in the context of the written description and prosecution history of the '831 patent leads to the conclusion that the term "board" must be limited to wood cut from a log," notwithstanding the doctrine of claim differentiation). Accordingly, BMI's arguments based on the doctrine of claim differentiation cannot stand.

VI. BMI's Dictionary Definition Approach Ignores the Specification

Although BMI parrots the words "ordinary and customary meaning," BMI shows no signs that it has even read the specification, the Webb articles incorporated by reference, or consulted experts to understand the underlying complex technology. Instead, BMI's understanding of "ordinary and customary meaning" relies on dictionary definitions and outdated case law repudiated by *Phillips*. "Ordinary and customary meaning" is the meaning a person of ordinary skill in the art at the time of invention would give to a claim term based on a reading of the patent documents, not a litigation-inspired meaning chosen from a general dictionary by a layperson. Rather "the person of ordinary skill in the art is deemed to read the claim term not

only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. The court cited to *Multiform Desiccants, Inc. v. Medzam, Ltd.,* 133 F.3d 1473, 1477 (Fed. Cir. 1998), as explaining the point well:

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention – the inventor's lexicography – must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same sources as would that person, viz., the patent specification and the prosecution history.

Instead, BMI relies on a line of outdated case law from 2002 to explain its approach to claim construction.[13] (Doc. No. 142 at pp. 10-11) For example, BMI quotes *CCS Fitness* to explain how ordinary meaning can be limited. Like *Texas Digital*, the *CCS Fitness* methodology was based on a "heavy presumption" of ordinary meaning based on dictionary definitions. *See CCS Fitness*, 288 F.3d at 1366 ("[W]e indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning … Our precedents show that dictionary definitions may establish a claim term's ordinary meaning.") The quote that BMI cites refers to the four ways to overcome that heavy presumption of ordinary meaning. (Doc. No. 142 at pp. 10-11) What BMI fails to recognize is that the *en banc* court in *Phillip*s repudiated this approach to claim construction as improperly restricting the use of the specification. See *Phillips*, 415 F.3d at 1320.

> Although the concern expressed by the court in Texas Digital was valid, the methodology it adopted placed too much reliance on extrinsic sources such as

[13] *CCS Fitness, Inc. v. Brunswick Corp*., 288 F.3d 1359 (Fed. Cir. 2002); *Omega*, 334 F.3d at 1324; *Teleflex*, 299 F.3d at 1326, *N. Telecom Ltd. v. Samsung Elec. Co*., 215 F.3d 1281 (Fed. Cir. 2000); *Rexnord Corp.*, 274 F.3d at 1347.

> dictionaries, treatises, and encyclopedias and too little on intrinsic sources, in particular the specification and prosecution history. While the court noted that the specification must be consulted in every case, it suggested a methodology for claim interpretation in which the specification is limited to determining whether the specification should be consulted only after a determination is made, whether based on a dictionary, treatise or other source, as to the ordinary meaning or meanings of the claim term in dispute. Even then, recourse to the specification is limited to determining whether the specification excludes one of the meaning derived from the dictionary, whether the presumption in favor of the dictionary definition of the claim term has been overcome by 'an explicit definition of the term different from its ordinary meaning,' or whether the inventor 'has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.' In effect, the Texas Digital approach limits the role of the specification in claim construction to serving as a check on the dictionary meaning of a claim term if the specification requires the court to conclude that fewer than all the dictionary definitions apply, or if the specification contains a sufficiently specific alternative definition or disavowal ... That approach, in our view, improperly restricts the role of the specification in claim construction.

Confusing the doctrine of prosecution disclaimer with the improper importation of limitations from the specification, BMI then cites to *Omega*, and three other cases for the proposition that it has not intentionally disclaimed or disavowed the scope of Claim 25. (Doc. No. 142 at p. 11) *Omega* established the doctrine of prosecution disclaimer, which states that a disclaimer in the prosecution history must be unmistakable to limit the claim. *Omega*, 334 F.3d at 1324. The citation of these cases in a section devoted to improper importation of limitations is confusing. The specific pages cited by BMI do not support BMI's importation of limitations argument; they refer to an entirely different doctrine.

Returning to its discussion of improper importation of limitations, BMI then quotes *Phillips* generally as warning against limiting the claims to the specific disclosed embodiments. BMI fails, however, to respond to Accuray's specific arguments that the patent's characterization of the invention limits the claims to the disclosed embodiment. In fact, BMI cites case law such as *Epistar* and *SciMed* that support Accuray's position that the asserted claims in the '283 patent

are limited to SARP and the particular cost function recited at column 13, including CDVH curves. For example, in *Epistar*, the court notes that where an inventor distinguishes an invention over the prior art in an unmistakable disavowal of those prior art features, the claim is limited. *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1336 (Fed. Cir. 2009) (citing *Phillips*, 514 F.3d at 1316). *See also Honeywell Int'l, Inc. v. ITT Indus., Inc*., 452 F.3d 1312, 1319-20 (Fed. Cir. 2006); *SciMed Life Sys.,Inc. v. Advanced Cardiovascular Sys., Inc*., 242 F.3d 1337, 1342-44 (Fed. Cir. 2001)).

BMI also cites to *SciMed* for the proposition that "one of the cardinal sins of patent law [is] reading a limitation from the written description into the claim," but that was merely SciMed's argument, not the holding of the case. *Id.* at 1340. In fact, the holding in *SciMed* is just the opposite. The court found that the district court properly read the claims in view of the specification, and that the claim term "inflation lumen" was limited to coaxial lumens based on the repeated characterization in the specification that the coaxial lumen configuration was a necessary element of all embodiments of the invention. *Id.* at 1341-44 ("The words "all embodiments of the present invention" are broad and unequivocal. It is difficult to imagine how the patents could have been clearer in making the point that the coaxial lumen configuration was a necessary element of every variant of the claimed invention."). *See also Marine Polymer,* 2012 U.S. App. LEXIS 5567, *17 (the specification supports a limited construction of "biocompatible") (citing *Netcraft Corp. v. eBay, Inc*., 549 F.3d 1394, 1398 (Fed. Cir. 2008) ("The common specification's repeated use of the phrase 'the present invention' describes the invention as a whole….); *Verizon Servs., Corp. v. Vonage Holdings Corp*., 503 F.3d 1295, 1308 (Fed. Cir. 2007) ("When a patent thus describes the features of the 'present invention' as a

whole, this description limits the scope of the invention."); *Honeywell Int'l,* 452 F.3d at 1318 (limiting claim to a fuel filter where specification refers to it as 'the present invention.'").

A. The Preambles of Claims 25 and 29 Are Limiting

BMI argues now that the preamble is not limiting and needs no construction. As in other instances in this case, BMI's position has changed over time. In its claim construction chart, BMI insisted on defining both the terms "apparatus," which appears only in the preamble of both claims 25 and 29, and "computer" which appears in the preamble of claim 29. (Doc. No. 131 at pp. 1-2, 9, 96) BMI attempted to define the term "apparatus" broadly for infringement purposes so that it could attempt to cover the entire CyberKnife radiation therapy system, or at least the entire MultiPlan Treatment Planning System. *See* Doc. No. 122 at p. 11, n. 10. BMI, however, never tells the Court "what the inventor has invented," but rather only that the claim terms are not limited in any way. Such a course leads straight to summary judgment of invalidity. *See, e.g., MySpace, Inc. v. Graphon Corp*., No. 2011-1149, 2012 U.S. App. LEXIS 4375, *9-11 (Fed. Cir. March 2, 2012), in which the court affirmed the district court's broad claim construction of "database" and grant of summary judgment of invalidity in light of the prior art. The court commented that the inventor could have avoided such a result by claiming less. *Id.* ("An inventor is entitled to claim in a patent what he has invented, but no more. He can, however, claim less, to avoid prior art or for any other reason.")

The preamble is limiting because it defines the scope of the claim as limited to optimization of a radiation beam arrangement (an array of beam weights) and, in particular, defines the scope of the term "apparatus" as limited to ***determining an optimized radiation beam arrangement***. As indicated by the preamble, the inventor chose to claim one aspect of the treatment planning system, the optimization of beam weights. The scope of the claim does not include treatment delivery or aspects of planning such as optimization of beam positions or beam

geometry. In other words, the claim covers an improved "optimizer," which is limited to a computer running optimization software with a specific optimization algorithm, SARP, to optimize beam weights and a specific cost function, the one disclosed in column 13 of the specification.[14] *See, e.g.,* Col. 9:29-30, 49-59, 59-64; see Fig. 5B; Col.10:31-52; Col. 12:27-47, 45-47. The language of the preamble does breathe life and meaning into the claim, and is therefore properly construed. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999).

B. The Term "Optimized Radiation Beam Arrangement" is Limited to the SARP algorithm

BMI argues that Accuray has improperly imported limitations into its proposed construction of "optimized radiation beam arrangement." (Doc. No. 142 at p. 12) Belatedly turning to the specification, BMI argues half-heartedly that the optimized radiation beam arrangement is described as "applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient…." (Doc. No. 142 at p. 13) That excerpt is not helpful; it only describes in general terms what an optimized radiation beam arrangement does, ***not what it is***.

BMI does not attempt to refute Accuray's position that "optimized" is a relative term. As explained in the intrinsic record, including the Webb articles incorporated by reference, and the supporting extrinsic evidence, including technical publications and the Rosen Declaration, one of skill in the art would interpret "optimized" based on a number of factors. (Doc. No. 138 at p. 22) Whether a radiation beam arrangement is "optimized" depends on the input parameters, the cost function, and the particular optimization algorithm used. In other words, different results (an entirely different radiation beam arrangement) would be obtained depending on which

[14]The term "optimization" is referenced in the specification 21 times: the term "optimized is referenced in the specification 35 times; the term "optimizer" appears in the specification once.

parameters are chosen. That is why Accuray included the language "based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm" in its construction of "optimized radiation beam arrangement." *See* Col. 9:29-48.

BMI then makes a series of incomprehensible and contradictory arguments about the inclusion of SARP into the cost function. First, BMI argues that Accuray improperly reads SARP methods into the cost function in Claim 25 because "***the present invention is distinguished over SARP***." (Doc. No. 142 at p. 13) BMI quotes a lengthy excerpt from the background section of the specification, but completely misunderstands what it says. The inventor was not distinguishing its optimization algorithm over SARP, but rather explaining the problems with prior art cost functions used with SARP. The inventor's solution to the problem was incorporating a "modified" cost function into the known SARP algorithm. *See* Col. 9:49-59. Second, BMI quotes another excerpt from the specification: "the cost function of the present invention *may be* easily incorporated into existing SARP algorithms by one skilled in the art." (Doc. No. 142 at p. 13) BMI argues that these two statements "clearly demonstrate that ***other computation methods*** exist to optimize treatment plans, and ***they are distinguished from the invention in the '283 patent***." *Id.* If "***they***" refers to "***other computation methods***," then BMI has made the illogical argument that those other computation methods are ***not*** part of the "invention in the '283 patent" either.

BMI then makes a feeble attempt at a claim differentiation argument, that "the claim language of Claims 3, 5, 19, 43, and 45 indicate that simulated annealing radiation therapy (sic) (SARP) is a method of calculation, and these claims are differentiated from the present claims in suit because there is a 'presumption that each claim in a patent has a different scope." (Doc. No. 142 at p. 14) BMI cites a few cases in a footnote and leaves it to the Court to fill in the details.

Is BMI seriously suggesting that claim 25 does not cover SARP?[15] As discussed in Accuray's Responsive Brief, and at section V above, BMI's claim differentiation argument has no merit.

BMI seems to be saying (all at the same time) that (1) SARP is excluded from the invention, (2) SARP can be part of the invention, (3) other "computation methods" are distinguished and excluded from the invention, and (4) claim differentiation means that the asserted claims cannot cover SARP. Following BMI's convoluted thinking, if SARP is not part of the invention, and other "computation methods" are not part of the invention, what is the invention? SARP is the *only* optimization algorithm disclosed in the specification. No other optimization algorithm is disclosed or even mentioned, and if BMI is suggesting that claim 25 covers another undisclosed optimization algorithm, it runs straight into invalidity for lack of written description and lack of enablement. *See* 35 U.S.C. § 112 ¶1; *Ariad, 5*98 F.3d at 1351 . In addition, a construction that excludes the preferred (or only) embodiment is rarely if ever correct. *Vitronics Corp., v. Conceptronic, Inc.*, 90 F.3d 1576, 1583-84 (Fed. Cir. 1996). BMI confirms with every argument it makes that it does not understand its own patent and has no basis for its infringement suit against Accuray.

C. "Optimized Radiation Beam Arrangement" Does Not Include Optimization of Beam Geometry and is Limited to the SARP Algorithm

BMI argues that "optimized radiation beam arrangement" includes the optimization of both beam geometry and beam weight. (Doc. No. 142 at p. 14) Turning to the specification as a last resort, BMI now argues that the specification discloses how to achieve optimal beam positions around the treatment field. *Id.* ***For the first time***, BMI cites to Col. 9:7-45 to support its construction of "optimized radiation beam arrangement." BMI did not cite to this portion of

[15] BMI concedes for Claim 29 that SARP is the optimization algorithm disclosed in the specification, but buries its head in the sand when it comes to Claim 25.

the specification in the Joint Disputed Claim Chart or in its Opening Brief, and is prohibited from doing so now.

Moreover, that excerpt does not disclose ***optimization of beam positions***.[16] BMI italicizes the first sentence in that excerpt, which refers in passing to beam arcs and generally explains the effect of modulating beam intensities. The excerpt indicates the relationship between dose and multiple beams hitting the target from different orientations, but does not indicate how many beams should be selected or from which orientation. In fact, the excerpt cited by BMI plainly states that, "The optimal beam arrangement is arrived at by ***computationally increasing the proposed beam weight*** iteratively…" As Accuray explained in its Responsive Brief at p. 11, the optimization of beam positions (or beam geometry) was beyond the skill of expert artisans at the time the '283 application was filed. That was in part why Dr. Webb simplified the optimization problem from 3D to 2D in his 1989 and 1991 articles. The inventor chose to claim a particular aspect of optimization -- the optimization of beam weights. The selection of the particular beams used to deliver the treatment plan is not disclosed anywhere in the patent. *See* Rosen Dec. at ¶¶ 94-96, 115.

Although BMI is correct that Figure 2 states that beam position and strength optimization is performed, there is absolutely no disclosure in the specification of how beams are selected or how ***beam position*** optimization is done. Dr. Webb explained in his 1989 article at page 1350 that the problem to be solved is "***determining the optimum weights for the beam elements of a beam at each orientation given the dose prescription***," and that "this problem is solved by the method of simulated annealing." The paper ***assumes*** that "the (now multi-element) beams are to

[16] BMI objects to the term "beam geometry," but that is how one of skill in the art would refer to selection of beams and beam positions around a treatment field. *See* Rosen Decl. at ¶60.

be arranged at appropriate orientations relative to the tumor volume." *Id.* Thus the optimization of beam positions was not considered, but rather the beam orientation was simply assumed.

That lack of disclosure regarding the selection of beams and optimization of beam positions in the '283 specification makes sense in the context of the type of system developed and used by NOMOS and the principal inventor, Mark Carol, at the time of invention. The Peacock Three Dimensional Conformal System, which was introduced in 1994, uses a rotating gantry, sequential arc technique, in which the treatment is delivered in multiple axial slices. (Ex. 2 at 56-57) Dr. Rosen explains a rotational gantry system in his declaration at ¶¶ 40-53. Further, as explained by Dr. Carol, the Peacock system delivers radiation through the Multileaf Intensity Modulating Collimator (MIMiC) which attaches to the gantry head of a standard linear accelerator. The MIMiC has opposing rows of 20 tungsten leaves, each of which projects to a 1 x 1 cm^2 field at isocenter in the open position. A single arc with the MIMiC treats a 2 cm length; longer fields are treated with sequential arcs with precision linear indexing of the couch. Each slice of the target region is treated with the MIMiC collimator during gantry rotation. After each rotation, the patient is moved in the horizontal direction so the next slice can be treated. See Dr. Carol's detailed explanation in his 1995 article (Ex. 2) at pages 56-57:

> The MIMiC narrows the beam coming down from the accelerator into two thin "slices," and then divides these slices into 40 smaller beams, 20 for each slice. Each of these "pencil beam can be turned on and off by driving a tungsten block into its path, called a leaf. A treatment is delivered in a rotational fashion functionally viewed as a series of fixed ports; every 5 degrees of rotation is treated as a separate port. ***As the gantry rotates around the patient with the accelerator turned on, turning an individual "pencil" beam on or off for a variable period of time during the 5 degree arc controls the effective attenuation of that beam during the 5 degree of arc treated as if it were a fixed port.*** This results in spatial modulation through temporally variable, "binary attenuation of the treatment beam. Because this modulation is delivered in a slice-by slice fashion, and a complete treatment is accomplished by stacking a series of slices, the term STACed Slice RT (spatial temporal attenuation modulated conformal radiation therapy) is used to describe Peacock's implementation technique.

> ***A rotation about the patient can only treat the equivalent of two slices through the patient; the table must successively indexed forward to treat the rest of the targets which are thicker than twice the width of an MIMiC treatment slice*** (1 or 2 cm…). The indexing/rotation process continues until the full target has been treated….
>
> ***Although*** planning is done on a slice-by-slice basis – ***the beam weights for a rotation around a single slice through the target are generated independent of all other slices through the target*** – dose simulation is volumetric.

Figure 5A of the '283 patent discloses that the Nomos Library 6MV is part of the Treatment Machine. As discussed above at section IIID, the NOMOS Library 6MV is a beam library used with the Corvus planning system. It contains parameters that describe the treatment machine, including fixed gantry positions.[17] The arc is typically 270 degrees, with beam positions at every 5 degrees. *Id.* Thus, Figure 5A clearly shows that the beam positions in the arcs are in the treatment machine and are pre-packaged in a library. The beam positions are separate from the planning goals and are not optimized as part of the optimization process. *See* Figure 5B, which states at the top, "Treatment Complexity, 1 cm Slices, 1 TA, 0," which shows that the system used is a rotational gantry system, treating in 1 cm slices. *See* Figure 5B at the bottom, "Simulated Annealing Parameters, Iterations, Start grain, End grain," which shows that simulated annealing is used.

BMI also argues that Accuray is attempting to narrow the scope of the claim by asserting that the only reference to beams is in "a 'SARP' portion of the specification (Col. 12:27-32)." As stated above, the only disclosed optimization algorithm is SARP, and column 12 provides the only detailed disclosure of how the SARP technique optimizes the beam weights. Column 12 relies heavily on the Webb articles, which are purportedly incorporated by reference, and Webb did not consider optimization of beam positions. BMI ignores the Webb articles, never

[17] *See, e.g.,* Lee, Jason et al., Intensity Modulated Radiation Therapy: An Introduction for Patients and Clinicians – Part II: Treatment Delivery and Clinical Applications," at Oncolink.org/treatment/article.cfm?c=5&s=33&id=183.

mentioning them in either its Opening or Reply briefs with respect to Claim 25, and thus cannot take a contrary position now.

D. "Proposed Radiation Beam Arrangement" is Limited to the SARP Algorithm

BMI argues that for the construction of "proposed radiation beam arrangement," Accuray has "cherry-picked" features of the preferred embodiment, the prior art and objects of the invention, and has "rewritten the claims to include features that fulfill the objectives of Accuray's non-infringement case." (Doc. No. 142 at p. 16) Like all of its arguments, BMI resorts to generalities, but fails to engage on the technology and explain why Accuray's proposed construction is wrong. Instead, BMI falls back on "ordinary meaning," relying on dictionary definitions. BMI's proffered construction, substituting "suggested" for "proposed" does not provide any insight as to what a person of ordinary skill in the art at the time of invention would have understood the claim term "proposed radiation beam arrangement" meant, in light of the entire patent documents, including the Webb articles purportedly incorporated by reference. BMI provides no explanation of how a proposed radiation beam arrangement is generated, and thus cannot counter Accuray's construction or supporting argument.

As discussed in Accuray's Responsive Brief at p. 25, the specification repeatedly refers to "a proposed radiation beam arrangement" as "proposed during a given iteration" of the SARP algorithm. *See, e.g.*, Col. 5:15-47; 6:26-7:30; 8:5-67; 9:29-42; claim 14. The Webb articles further disclose how the SARP algorithm generates a proposed array of beam weights at each iteration of the algorithm. *See* Doc. No. 131, Ex. 4 at 1352-58. If BMI had bothered to read the Webb articles, instead of ignoring them at every turn, it might understand what a proposed radiation beam arrangement means in the context of its own patent.

Further, BMI conceded in its opening brief that the term "proposed radiation beam arrangement" could mean "an array of beam weights" in light of the disclosure in the specification. (Doc. No. 134 at pp. 8, 10) As discussed above at section VI.C, the specification does not disclose optimization of beam positions around the treatment field, and the state of the art at the time the '283 patent application was filed supports Accuray's construction. *See* Rosen Dec. at ¶ 194-96. Here, the patentee chose to claim only the optimization of beam weights. In the absence of any disclosure, BMI's alternate construction would render the '283 patent invalid under 35 U.S.C. § 112 for lack of written description and/or lack of enablement. *See* 35 U.S.C. § 112 ¶1; *Ariad Pharms., Inc., 5*98 F.3d at 1351.

BMI further argues that the prosecution history does not support Accuray's construction because the applicant did not make a clear and unambiguous disavowal of the scope of the term. Doc. No. 142 at 16-17. The prosecution history indicates otherwise. The examiner rejected, *inter alia*, claims 26 and 31 (which issued as claims 25 and 29) under 35 USC §102(e) as anticipated by Leber et al. The examiner stated that "Leber shows all of the features of the instant invention including radiation (therapy) beam optimization to a target volume and minimizing radiation to a structure volume, using a computer to modify the beam arrangement, and rejecting the new arrangement if it has a lesser correspondence to the desired radiation prescription (column 4 line 5- column 6 line 2)." (Doc. No. 131, Ex. 2 at p. 2) The examiner further stated that the claims that depended from the rejected independent claims "are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." *Id.* In response, the applicant amended the claims, including claims 26 and 31 to add the phrase "***wherein the proposed***

radiation beam arrangement is changed by changing the beam weights" to overcome the rejection over Leber.[18]

BMI cites to *Computer Docking* and *Elbex* to support its position, but the doctrine of prosecution disclaimer is typically used to determine whether ***arguments*** made by the applicant during prosecution to distinguish the invention over the prior art disclaim subject matter. *Computer Docking Station Corporation v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008). Here, the applicant simply acquiesced in the Examiner's rejection and amended the claims as directed. Amending the claims as directed by the Examiner is a clear surrender of the subject matter. *Id.* at 1379 (when a patent applicant surrenders claim scope during prosecution before the PTO, the ordinary and customary meaning of a claim term may not apply). Construing the claim broadly in the face of the prosecution history can only lead to invalidation over Leber and over prior art references. *See Omega*, 334 F.3d at 1323-24 (citing *Graham v. John Deere Co*., 383 U.S. 1, 33 (1966) (ruling, in addressing the invalidity of the patents in suit, that "claims that have been narrowed in order to obtain the issuance of a patent by distinguishing the prior art cannot be sustained to cover that which was previously by limitation eliminated from the patent").

E. Further Adapted to Computationally Change the Proposed Radiation Beam Arrangement is Limited to SARP

BMI argues that "Accuray attempts to incorporate the SARP algorithm into the claim scope by citing to the specification and thus ignoring the ordinary and customary meaning of the term at issue." (Doc. No. 142 at 18) This statement is simply wrong as a matter of law under *Phillips*. As discussed in Accuray's Responsive Brief at p. 15, ordinary and customary meaning

[18] Leber disclosed, inter alia, "using ***simulated annealing*** to optimize a plan based on criteria or predetermined parameters selected by the dose planner related to involvement, coverage, ***beam arc***, inhomogeneity, or other specifications of the plan." *See, e.g.*, Col. 4:30-45. Leber did not disclose optimizing the plan by changing the beam weights.

is determined from the perspective of one of skill in the art in light of the specification, and thus Accuray's claim construction, and inclusion of the SARP algorithm, is appropriate.

BMI argues that "[e]ven though Leber describes a type of computation algorithm called a "Dynamically Penalized Likelihood (DPL) iterative algorithm, the Examiner maintained that such an algorithm met the features recited in Claim 25. (Doc. No. 142 at p. 18) BMI misinterprets and mischaracterizes the prosecution history. The applicant mistakenly described Leber: "***U.S. Patent No. 5,602,892***, to Leber et al." and as disclosing "[t]he preferred method and apparatus for solving the numerical optimization problem comprises a computer running a new Dynamically Penalized Likelihood (DPL) iterative algorithm (Col. 3:59-67-4:1)." *See* Doc. No. 131, Ex. 3 at 6-7. A search of Leber, however, reveals that that the DPL algorithm is not disclosed anywhere in the specification, but rather was disclosed in Llacer, the other prior art reference cited in the Office Action. *See id*. Indeed, the applicant had the correct patent number, but the wrong inventor name. The applicant was actually describing ***Llacer, USPN 5,602,892***, ***not Leber, USPN 5,513,238***. *See* Doc. No. 131, Ex. 2 at p. 3.

In contrast, the Leber specification plainly discloses the use of simulated annealing at column 4, lines 30-36: "As an illustration of the way that these parameters can be used to automatically compute a dose plan in a computer workstation, ***we could take the process of so-called simulated annealing*** to optimize a plan based on criteria or predetermined parameters selected by the dose planner related to these involvement, coverage, beam arc, inhomogeneity or other specifications of the plan." BMI's conclusion, "that the Examiner determined that Claim 25 was not limited to simulated annealing algorithm (SARP)" completely falls apart under closer scrutiny of the prosecution history.

F. The Construction of "At Each Iteration" is limited SARP

BMI argues that "at each iteration" is not limited to the SARP algorithm. Again, BMI refuses to engage on the technology and refuses to acknowledge the Webb articles, which explain in great detail what "at each iteration" means in the context of the '283 patent. From the perspective of one skilled in the art, the term "at each iteration" is consonant with simulated annealing, which is an iterative algorithm and the only optimization algorithm disclosed in the specification. BMI has provided no contrary explanation.

Grasping at straws, BMI argues that Accuray's contention that "at each iteration" is limited to SARP is supported only by the sequence of sentences in the specification. (Doc. No. 142 at p. 20) The specification clearly states at Col. 9, 29-49, after describing the optimization steps, that it is SARP that performs the optimization. BMI again reveals its willful ignorance of the technology and "what the inventor actually invented," arguing that "the specification makes no mention that the iterative function is done by using simulated annealing (SARP) with a cost function to determine the beam weight." BMI's argument is specious -- that is exactly what the Webb articles are all about. *See* Col. 12:27-45 and articles cited therein.

G. BMI's Construction of Cost Function Ignores the Disclosure in Column 13 and Would Render the Claim Invalid Over the Prior Art

BMI argues that Accuray improperly imports a limitation from the specification by limiting the cost function to the steps described in Column 13:4-39. (Doc. No. 142 at p. 21) As stated in Accuray's Responsive Brief at section V.D.1.a, the specification repeatedly refers to the "cost function of the present invention" as the specific cost function disclosed in column 13. In fact, the patentee concedes that everything in the patent is known in the art except the specific cost function. BMI provides no specific response to Accuray's arguments, relying only on "ordinary meaning" and column 13:1-4 to support its construction. BMI's construction of "cost

function" as any cost function cannot possibly be correct because it would render the '283 patent is invalid over the Webb articles incorporated by reference and every other prior art reference that discloses treatment planning optimization. *See Phillips*, 415 F.3d at 1328 (applicability of doctrine to construe claims to preserve their validity "depends on the strength of the inference that the PTO would have recognized that one claim interpretation would render the claim invalid, and that the PTO would not have issued the patent assuming that to be the proper construction of the term.")

BMI concedes that the cost function is explicitly defined in the specification, but ignores the detailed disclosure in column 13. (Doc. No. 142 at p. 22). The explicit definition of cost function includes column 13:4-39, which starts off with the phrase, "***In the cost function of the present invention*,"** and then goes on to describe the specific formulas. Nothing could be clearer. *See Marine Polymer*, 2012 U.S. App. LEXIS 5567, *17 (the specification supports a limited construction of "biocompatible") (citing *Netcraft Corp. v. eBay, Inc*., 549 F.3d 1394, 1398 (Fed. Cir. 2008) ("The common specification's repeated use of the phrase 'the present invention' describes the invention as a whole…."); *Verizon Servs., Corp. v. Vonage Holdings Corp*., 503 F.3d 1295, 1308 (Fed. Cir. 2007) ("When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention."); *Honeywell,* 452 F.3d at 1318 (limiting claim to a fuel filter where 'the written description refers to the fuel filter as 'this invention' or 'the present invention.'").

H. BMI's Construction of "Leads to Greater Correspondence" Ignores the Specification

BMI's argument that the construction of "leads to a greater correspondence to the desire dose prescription" is not limited to SARP boils down to an improper importation of limitations argument. Again, BMI does not engage on the technology, but rather falls back on so-called

"plain" meaning. The claim language is ambiguous, and an understanding must be pieced together from the specification, including the Webb articles, and the understanding of one skilled in the art, based on the extrinsic evidence, including Rosen's declaration and the technical publications that reflect the background of the technology and the state of the art. *See* Doc. No. 138 at pp. 33-35, 37-40, 45-49.

BMI argues first that Accuray does not address "the desired dose prescription." BMI is wrong. Accuray construed the entire phrase "partial volume data associated with the desired dose prescription," as shown on p. 34-35, and provides voluminous support from the intrinsic record for its construction on pp. 38-39 of its Responsive Brief. For example, on page 38, Accuray further states, "The predetermined desired dose prescription encompasses the clinical goals the user has, as exemplified by the partial volume data." *See* Col. 10:53-11:35. Further, as explained at pp. 42-43, one of skill in the art would have understood that partial volume data associated with the predetermined desired dose prescription referred to the partial volume data for each target and structure entered into the Prescription Panel by the user, and that such partial volume data was used to generate a CDVH curve for each target and structure that represented the desired dose prescription prescribed by the physician.

BMI complains that Accuray's construction for "leads to a greater correspondence…" is 132 words long, but constructions are frequently longer than the claim term or claim phrase itself, unless, of course, one uses dictionary definitions. Before attempting to construe "leads to a lesser correspondence … greater correspondence," however, the concepts of (1) "partial volume data associated with the desired dose prescription," (2) "partial volume data associated with the proposed radiation beam arrangement," (3) "to approach correspondence of partial volume data associated with the proposed radiation beam arrangement with partial volume data

associated with the desired dose prescription," must to be understood. BMI has not even attempted to rebut Accuray's constructions with arguments based on the technology or the intrinsic record.

Moreover, these claim terms are not easy concepts to convey to the layperson. First, the partial volume data includes multiple data points for the target and each involved structure. All of those partial volume data as entered by the user into the Prescription Panel make up the partial volume data associated with the desired dose prescription, as discussed above and in Accuray's Responsive Br. at pp. 37-38. Further, as explained at pp. 38-40, the phrase "partial volume data associated with the proposed radiation beam arrangement" is inextricably intertwined with the SARP algorithm because it is generated at each iteration of that algorithm. Although the specification refers only to CDVH curves, a meaning can be found if one understands that CDVH curves and partial volume data are used interchangeably in the '283 patent. As explained at pp. 39-40, at each iteration of the SARP algorithm, the cost function measures how close the partial volume data associated with the proposed radiation beam arrangement is to the partial volume data associated with the desired dose prescription for the target and each structure. In other words, the cost function determines a total cost. BMI cannot explain why this construction is technically wrong.

Importantly, BMI does not respond to Accuray's argument that the words "greater correspondence" and "lesser correspondence" implies that there must be a comparison between the cost of the proposed radiation beam arrangement of the current iteration with the cost of the proposed radiation beam arrangement of the previous iteration of the SARP algorithm. *See* Doc. No. 138 at pp. 46-48. Instead, BMI focuses myopically on the inclusion of the SARP algorithm,

and ignores what it cannot explain. The only disclosure in the specification for this limitation, however, is stated in terms of the SARP algorithm, and thus Accuray's construction is correct.

I. Accuray Does Not Add a Negative Limitation to its Construction of Changing the Beam Weights

BMI argues that Accuray attempts to add a negative limitation into the phrase "changing the beam weights." BMI disagrees with Accuray's statement that the Examiner required the applicant to amend every claim to include "changing the beam weights," arguing that Claims 1, 4 and 14 were allowed without amendment. Although BMI is technically correct that the Examiner allowed claims 1, 4 and 14 without amendment, that correction does not help its larger argument. The reason for allowance of claims 1, 4 and 14, which are method claims, was because they included CDVH limitations, which were not addressed by Leber. *See* Doc. No. 131, Ex. 2 at p. 3. As discussed above in section VI.D, the Examiner rejected claims 22, 25, 26, 28, 31, 33, 36, 38, 49, 50 and 52 under 35 USC §102(e) as anticipated by Leber, and objected to claims 23,24, 27, 29, 30, 32, 34, 35, 37, 40 and 51 as being dependent upon a rejected base claim, but allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. (Doc. No. 131, Ex, 2 at pp. 2-3) Thus, with BMI's minor correction, Accuray's argument is the same.

BMI cites no case law for its argument that Accuray is attempting to improperly include a negative limitation that does not appear in the claim. BMI cites case law only for the irrelevant proposition that a claim using "comprising" is "open-ended." The Examiner required the applicant to amend the asserted claims to add the limitation "wherein the proposed radiation beam arrangement is changed by changing the beam weights," to overcome the anticipation rejection over Leber, and thus this limitation has patentable weight. Leber disclosed using "***simulated annealing*** to optimize a plan based on criteria or predetermined parameters selected

by the dose planner related to these involvement, coverage, ***beam arc***, inhomogeneity or other specifications of the plan," and did not disclose optimization by changing beam weights. (Doc. No. 131, Ex. 2 and Doc. No. 131, Ex. 6 (Leber patent))

In its Opening Brief, BMI conceded that the specification supports a construction "radiation beam arrangement" limited to an array of beam weights. *See* Doc. No. 134 at pp. 8, 10; Col. 9:29-34 ("The optimizer of the present invention computes an optimized treatment plan or beam arrangement, which should be understood to include ***either*** the optimal beam positions around the treatment field, the optimal array of beam weights, or beam intensities, otherwise known as an intensity map or fluence profile ***or both***."). There is no disclosure of "optimal beam positions around the treatment field," and thus the proper construction must be "an array of beam weights."

BMI again argues that Accuray's construction of "changing the beam weights" improperly imports limitations by defining beam weights as "small quanta of positive or negative beam intensities." "Adding and subtracting small quanta of positive or negative beam intensities" comes straight from the Webb articles, which were incorporated by reference in the specification. *See* Col. 12:30-45; Doc. No. 131 at Ex. 4. Webb explains that simulated annealing works by adding or subtracting very small amounts (or quanta) of beam intensity randomly to each beamlet at each iteration, and running the algorithm through millions of iterations to obtain an optimized array of beam weights. *Id.*

Buried in its Reply Brief at page 26, BMI for the first time makes the ludicrous argument that "changing of beam intensities allows for the removal of the entire beam and adding an entirely new beam." Of course, BMI provides absolutely no intrinsic record support for this assertion, because there is none to be found. Nor does BMI argue that one of skill in the art

would read the claims that way. Indeed, BMI cannot even point to a dictionary definition that would support this expansion from the claim term "changing the beam weights." BMI's proposed construction reads out the term "weights" from this limitation, in contravention of black letter patent law that states every word in a claim has meaning. *Merck & Co. v. Teva Pharms. USA, Inc*., 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.")

Moreover, neither simulated annealing (nor any other optimization algorithm) optimizes beam weights ***by adding or subtracting an entire beam.*** The specification and the Webb articles incorporated by reference, disclose that each beam is divided into a large number of small beamlets, and the beam weight is changed for each beamlet individually. *See* Col. 12:30-34 ("A SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of small beams, each of which hit the target.") This disclosure is consistent with how one of ordinary skill in the art would have understood how simulated annealing works. Moreover, even if the entire weight was removed from a beamlet, the beamlet would still exist as part of beam, which has geometry (orientation and direction). Conceptually, adding or subtracting beam weight (beam intensity) is different from adding or subtracting an entire beam, which has both intensity and geometry. BMI concedes, as it must, that beam position and beam intensity are two different aspects of radiation beams. (Doc. No. 142 at pp. 14-15) *See, e.g*., Col. 9:29-34. Changing the beam weights cannot mean changing both beam position and beam intensity. BMI's theory is speculative at best, as it has absolutely no intrinsic or extrinsic evidentiary support.

BMI argues that Accuray's "adding or subtracting small quanta" limitation limits the scope of the invention by not allowing smaller or bigger changes for faster and more efficient

optimization. (Doc. No. 142 at p. 26) BMI drastically expands the claim and attempts to untether it from the specification. Without a technical explanation, grounded in the intrinsic record, of how changing the beam weights can also change beam geometry, BMI's construction is simply insupportable. Only by willfully ignoring the Webb articles, which provide the only detailed disclosure of how the only optimization algorithm, simulated annealing (SARP), works, can BMI make this argument. And now Accuray and the Court know why. If BMI acknowledges Webb at all, its far-fetched infringement theory evaporates into thin air.

J. Partial Volume Data and CDVH Curves are Interchangeable

BMI argues that Accuray incorrectly states that partial volume data and CDVH can be used interchangeably. BMI argues that it is a matter of common sense that the two cannot be interchangeable if "partial volume data is used to generate CDVH curves." (Doc. No. 142 at p. 27) BMI ignores the fact that the specification also says that CDVH curves can be used to generate partial volume data. *See* Doc. No. 138 at p. 37. In other words, it is reciprocal. Figures 5A and 5B show the interchangeable nature of CDVH curves. Figure 5A shows the input of partial volume data for the target and each structure. Figure 5 B shows the CDVH curves generated from that partial volume data. A physician could just as easily start with CDVH curves and generate the partial volume data. Claim drafters can and do use different words to define the same subject matter. *Curtiss-Wright*, 438 F.3d at 1380-81.

BMI makes the unsupported assertion on page 27 of its Reply that "CDVH curves do not display information about the maximum dose structure of the volume and minimum dose structure simultaneously." The statement appears to have typographical errors, is incomprehensible and technically inaccurate, is not supported by any intrinsic or extrinsic evidence, and thus should be disregarded. BMI again makes a feeble claim differentiation argument, pointing to claim 26. As discussed above at section V, claim differentiation is not a

hard and fast rule, and where there is a conflict between the specification and the doctrine, the specification wins. Here, the cost function cannot calculate a cost without generating CDVH curves for each target and each structure, dividing the curves into zones, weighting those zones differentially, and calculating a total cost for the proposed radiation beam arrangement of each iteration. Accordingly, Accuray's construction is correct.

VII. BMI Fails to Address Accuray's Specific Arguments Regarding Claim 29

Accuray's Responsive Claim Construction Brief identified several defects in BMI's constructions for claim 29, which are undisputed by BMI. Indeed, BMI's Reply Brief fails to address any of Accuray's claim construction arguments for claim 29, other than to argue that "the preambles of claims 25 and 29 are not limiting" and that claim 29 is not indefinite. (Doc. No. 142. at pp. 12-14, 30-32). For example, as stated in Accuray's Responsive Brief at pp. 49-59, BMI points to a computer running the SARP algorithm as the corresponding structure for each of the claimed means limitations, but fails to limit its construction to that structure. *Biomedino, LLC v. Waters Techs. Corp*., 490 F.3d 946, 948 (Fed. Cir. 2007) (holding that indicated structure must limit claim to prevent pure functional claiming.); *Mettler Toledo, Inc. v. B-Tek Scales, LLC*, Case Nos. 2011-1173, 2011-1200, 2012 U.S. App. LEXIS 2434, at *8-9 (Fed. Cir. 2012). Moreover, as set forth in Accuray's brief at pp. 49-59, BMI does not mention the Webb articles, which provide the detailed disclosure of SARP, in its construction of the phrase "means for computationally obtaining a proposed radiation beam arrangement." BMI's construction violates the principle that where "the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the [corresponding] structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm.'" *Dealertrack Inc. v. Huber,* Nos. 2009-1566, 2009-1588, 2012 U.S. App. LEXIS 1161, at *33-34 (Fed. Cir. 2012); citing *Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game*

Tech., 521 F.3d 1328, 1333 (Fed. Cir. 2008); *WMS Gaming v. International Game Technology*, 184 F.3d 1339, 1349 (Fed. Cir. 1999)). For the same reasons as discussed above, BMI's construction is incorrect, and BMI does not dispute these points in its Reply.

VIII. BMI's Construction Renders Claims 25 and 29 Indefinite

A. Claim 25 is Indefinite as a Hybrid Claim

In response to Accuray's contention that claim 25 improperly mixes two separate statutory classes of invention, BMI argues that "the functional language in claim 25 merely describes the capabilities of the computer." (Doc. No. 142 at pp. 29-30) BMI misses the point. The problem with claim 25, as in *IPXL*, is that the claim language does not apprise the public as to when infringement occurs. This is the hallmark of indefiniteness. *IPXL Holdings, L.L.C. v. Amazon.com, Inc*., 430 F.3d 1377, 1383-84 (Fed.Cir. 2005).

Specifically, the preamble indicates that the patentees sought to claim "an apparatus" including a "computer." However the claim limitations references the use of the apparatus to perform a method step, *e.g.,* to "computationally obtain a proposed radiation beam arrangement," "computationally change the proposed radiation bean arrangement iteratively," "chang[e] the beam weights," "incorporate a cost function at each iteration . . ." and "to reject the change of the proposed radiation beam arrangement . . . and to accept the change of the proposed radiation beam arrangement . . . ." Here, as in *IPXL*, it is unclear whether infringement of claim 25 occurs when an engineer ***creates an apparatus*** to "determine an optimized radiation beam arrangement" that is capable of performing the recited functions, or whether infringement occurs when a clinician actually ***uses the apparatus*** to "determine an optimized radiation beam arrangement" by "computationally obtain[ing] a proposed radiation beam arrangement," "computationally chang[ing] the proposed radiation bean arrangement iteratively," "changing the beam weights," "incorporate[ing] a cost function at each iteration . . ." and "reject[ing] the change of the

proposed radiation beam arrangement . . . and . . . accept[ing] the change of the proposed radiation beam arrangement . . . ." *Id.* at 1383-84. Who is the potential infringer – the engineer or the clinician? Because claim 25 recites both an apparatus and a method for using that apparatus, the public is left to guess. BMI could not (or would not) answer this question in its Reply Brief. *See* Doc. No. 142 at pp. 28-30. As the Federal Circuit held in *IPXL*, claim 25 "is not sufficiently precise to provide competitors with an accurate determination of the metes and bounds of protection involved" and is thus invalid under §112, ¶2. *IPXL*, 430 F.3d at 1384.

B. Claim 29 is Indefinite For Failure to Disclose a Specific Structure

BMI cannot genuinely claim to be surprised by Accuray's contention that Claim 29 is invalid as indefinite for failure to disclose a specific structure corresponding to each of the functional limitations recited in the claim. *See* Doc. No. 142 at p. 31. BMI was put on notice of this contention when Accuray served its Invalidity Contentions pursuant to LPR 3-4.

BMI expounds on the law of indefiniteness and means plus function claims, but devotes little attention to the substance of Accuray's arguments. As set forth in Accuray's Responsive Brief, for each alleged "means plus function" limitation of claim 29, BMI contends that the corresponding structure is "a computer programmed" to perform the recited functional limitation. However, the '283 patent specification itself does not describe any specific structure (*i.e.*, algorithm) which performs the recited functions of claim 29, in violation of § 112. *DealerTrack,* 2012 U.S. App. LEXIS 1161, at *33-34 (holding that where "the disclosed structure is a computer … programmed to carry out an algorithm, the [corresponding] structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm."). BMI argues that "the '283 patent is replete with descriptions of the structure and algorithms corresponding to the functions recited in Claim 29" (Doc. No. 142 at p. 32), but does not cite to even a single line from the specification which describes the

structure of the simulated annealing algorithm. The specification repeatedly states that "simulated annealing" is the algorithm that is used, but purports to incorporate by reference Steve Webb's articles describing the simulated annealing algorithm at Col. 13:34-45 to provide the detailed disclosure.

BMI suggests that it is not a fatal defect because "SARP algorithms were well understood by those skilled in the art at the time Best Medical filed its patent application." (Doc. No. 142 at p. 32) But this is not the law. *Pressure Prods. Med. Supplies, Inc. v. Greatbatch Ltd.*, 599 F.3d 1308, 1317 (Fed. Cir. 2010). In *Biomedino*, the Federal Circuit held that a statement in the specification that known techniques or methods can be used does not disclose structure under § 112 and that "to conclude otherwise would vitiate the language of the statute requiring corresponding structure, material, or acts described in the specification. *Biomedino*, 490 F.3d at 948. As the '283 specification fails to disclose the structure of the SARP algorithm corresponding to the "means" limitations, other than by reference to Webb, this claim is invalid as indefinite. *Id.*

For the foregoing reasons, and those set forth in Accuray's Responsive Claim Construction Brief, the Court should adopt Accuray's proposed constructions.

Dated this 26th day of April, 2012.

/s/ Kirsten R. Rydstrom
Kirsten R. Rydstrom
Pa. I.D. No. 76549
REED SMITH LLP
435 Sixth Avenue
Pittsburgh, PA 15219
412-288-7284
fax: 412-288-3063
krydstrom@reedsmith.com

Madison C. Jellins
HelixIP LLP
400 Seaport Court
Suite 105

Redwood City, CA 94063
650-474-0240
mcjellins@helixip.com

Janice Christensen
HelixIP LLP
New York
Counsel for Defendant,
Accuray Incorporated
650-474-0240
jchristensen@helixip.com

CERTIFICATE OF SERVICE

I hereby certify that on April 26, 2012, I electronically filed the foregoing document with the clerk of court for the U.S. District Court, Western District of Pennsylvania, using the electronic case filing system of the court. The electronic case filing system will send notification of such filing to all counsel of record. Counsel may access such document using the Court's system.

/s Kirsten R. Rydstrom
Attorneys for Defendant Accuray Incorporated

Dated: April 26, 2012